REMARKS

Introductory Comments:

Claims 1, 2, 6-14 and 16-26 were examined in the Office Action under reply and stand rejected (1) under 35 U.S.C. §102; and (2) under the judicially created doctrine of obviousness-type double patenting. These rejections are respectfully traversed as discussed more fully below.

Applicant notes with appreciation the apparent withdrawal of the previous rejections under 35 U.S.C. §102 over Kay and Couto, as well as the rejection under 35 U.S.C. §103 over Kay in view of Couto, as these rejections were not reiterated.

Overview of the Above Amendments:

Claims 8-12 and 21-26 have been cancelled herein. Claims 1 and 13 have been amended to recite that the rAAV virions are delivered "to the bile duct system or to the ducts of the submandibular gland." New claims 27 and 28 have been added. Claims 27 and 28 are analogous to amended claims 1 and 2, respectively, but do not recite that the vector comprises a gene encoding Factor IX. Support for the amendments and new claims can be found in the claims as originally filed, as well as throughout the specification at, e.g., page 7, lines 1-3.

The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications hereof containing the cancelled or unamended claims.

Rejections Under 35 U.S.C. §102:

Claims 1, 2, 6-14 and 16-26 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent 6,156,303 to Russell et al. ("Russell") as evident by U.S. Patent No.

6,200,560 to Couto et al. ("Couto"). The Office asserts Russell "teaches a method of administering rAAV (AAV3B or AAV6) into an individual systemic or locally a human Factor IX and expressing the Factor IX in hepatocyte cells of the individual" and that Couto "teaches that hemophilia is a clotting deficiency." Office Action, pages 2-3, bridging paragraph. However, applicant respectfully submits Russell does not anticipate the present claims.

The law is clear that in order to anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986). *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clar Corp.* 713 F.2d 760, 771, 218 USPQ 2d 781, 789 (Fed. Cir. 1983, cert. denied, 465 U.S. 1026 (1984)).

Russell does not describe delivery of recombinant AAV virions via a duct, let alone via the bile duct or the ducts of the submandibular gland as claimed herein, and therefore cannot anticipate the present claims. Accordingly, withdrawal of this basis for rejection is respectfully requested.

Claims 1, 2, 11-14 and 16-20 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,670,176 to Samulski et al. ("Samulski") as evident by Couto. The Office argues Samulski "teaches a method of treating hemophilia in a human comprising administering to the liver of a human a rAAV comprising a nucleotide sequence encoding a Factor IX protein" and that Couto "teaches that 85% of the human population is seropositive for AAV-2 serotype." Office Action, pages 3-4, bridging paragraph. However, applicant respectfully disagrees.

In particular, Samulski pertains to the use of a liver-specific promoter for expression of a gene in liver cells. All of the examples pertain to delivery *in vitro* to

various cell types. There is absolutely no discussion regarding *in vivo* administration to the bile duct or to the ducts of the submandibular gland. Thus, as with Russell described above, Samulski also does not anticipate the present claims. Accordingly, withdrawal of this basis for rejection is also requested.

Claims 1, 2, 6-10, 13, 14 and 16-26 were rejected under 35 U.S.C. §102(e) as anticipated by U. S. Patent No. 6,093,392 to High et al. ("High") as evident by Couto. The Office argues High claims the same subject matter as the claims herein. However, as explained above, all of the present claims pertain to delivery of rAAV virions "to the bile duct system or to the ducts of the submandibular gland." High does not teach, suggest or claim delivery as now claimed by applicant. In fact, High nowhere even discloses delivery to the liver. Rather, the examples pertain to delivery into muscle. Thus, the rejection over High has also been overcome.

The Double Patenting Rejection:

Claims 1, 2, 6-10, 13, 14 and 16-26 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 3 and 8 of High, in view of Couto. The Office asserts "the claims of the instant application and patent '392 in view of Couto are obvious variants of one another." Office Action, page 7. Moreover, the Office states these claims are "directed to an invention not patentably distinct from claims 3 and 8 of commonly assigned patent 6,093,392." However, applicants disagree.

In particular, claims 3 and 8 of High do not pertain in any way to delivery via the bile duct or submandibular gland. As explained above, High nowhere speaks to delivery into liver, let alone ductal delivery such as into the bile duct or the ducts of the submandibular gland. Thus, an obviousness-type double patenting rejection of the present claims over High is not warranted. Withdrawal of the double patenting rejection is therefore earnestly solicited.

CONCLUSION

Applicant respectfully submits that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested. If the Examiner notes any further matters which he believes may be resolved by a telephone interview, he is encouraged to contact the undersigned by telephone at 650-493-3400.

Respectfully submitted,

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